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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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10/624,915

07/22/2003

D. Russell Pflueger

D-3077

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09/21/2006

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EXAMINER

PATEL, NIHIR B

ART UNIT

PAPER NUMBER

3743

DATE MAILED: 09/21/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

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|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/624,915 | PFLUEGER ET AL. | |
| | Examiner | Art Unit | |
| | Nihir Patel | 3743 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 12 July 2006.
2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 52-55, 66-68 and 70-92 is/are pending in the application.
4a) Of the above claim(s) _____ is/are withdrawn from consideration.
5) ☐ Claim(s) _____ is/are allowed.
6) ☒ Claim(s) 52-55, 66-68 and 70-92 is/are rejected.
7) ☐ Claim(s) _____ is/are objected to.
8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>08.11.2006</u> | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims **52-55, 66-68, 70, 71, 73-77, 79 and 80** are rejected under 35 U.S.C. 102(b) as being anticipated by Conrad et al. (US 6,250,307).
3. **As to claim 52**, Conrad discloses a method step that comprises providing an appliance in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal (**see figures 6, 7, 11, 12, 22 and 23**), the appliance so provided having at least two laterally positioned elements substantially longitudinally spaced apart from each other and being effective in treating at least one of sleep apnea and snoring (**see abstract**).
4. **As to claim 53**, Conrad discloses a method step wherein the appliance, when so provided, is effective in maintaining patency of the oropharyngeal region during natural sleep of the human or animal without causing substantial interference with at least one natural function of the epiglottis (**see column 4 lines 44-55**).
5. **As to claim 54**, Conrad discloses a method step that includes inserting the appliance into the oropharyngeal region while the appliance is in a first configuration and allowing the appliance to reconfigure to a second configuration within or in proximity to the oropharyngeal region (**see column 4 lines 5-15**).

6. **As to claim 55**, Conrad discloses a method of inserting the appliance into the oropharyngeal region through a mouth or a nose of a human or animal (see **figure 3**).
7. **As to claim 66**, Conrad discloses a method step of placing the appliance at least partially in or beneath the mucosal layer of the lateral and posterior walls of the oropharyngeal region (see **figures 6, 7, 11, 12, 22 and 23**).
8. **As to claim 67**, Conrad discloses a method step of placing the appliance completely across the posterior wall of the oropharyngeal region (see **figures 6, 7, 11, 12, 22 and 23**).
9. **As to claim 68**, Conrad discloses a method step of providing the appliance in a deformed first configuration, inserting the appliance into the oropharyngeal region and allowing the appliance to configure to a deployed second configuration within the oropharyngeal region (see **column 5 lines 51-67 and column 6 lines 1-9**).
10. **As to claim 70**, Conrad discloses a method step of providing at least one of the elements extending across the posterior wall of the oropharyngeal region (see **figures 6, 7, 11, 12, 22 and 23**).
11. **As to claim 71**, Conrad discloses a method step wherein the at least two elements are coupled together (see **figures 17 and 18**).
12. **As to claim 73**, Conrad discloses a method step wherein the appliance has a lateral dimension and a longitudinal dimension perpendicular to the lateral dimension which is less than the lateral dimension when the appliance is so provided (see **figures 17 and 18**).
13. **As to claim 74**, Conrad discloses a method wherein the appliance is sized and structured so that each of the at least two elements extend across the posterior wall and at least a portion of the lateral walls when the appliance is so provided (see **figure 11**).

14. **As to claim 75**, Conrad discloses a method wherein the appliance is sized and structured so that the at least two elements extend across the posterior wall and at least a portion of the lateral walls when the appliance is so provided (**see figure 11**).
15. **As to claim 76**, Conrad discloses a method step wherein the appliance has an open concave loop when so provided (**see figure 11**).
16. **As to claim 77**, Conrad discloses a method step wherein the appliance, when so provided, is effective to support or reinforce the oropharyngeal region without reacting with tissue in the oropharyngeal region (**see figure 11**).
17. **As to claim 78**, Conrad discloses a method step wherein the appliance comprises resilient wire (**see figure 17 and 18**).
18. **As to claim 79**, Conrad discloses a method step wherein the appliance is made of biocompatible metal (**see column 5 lines 50-55**).
19. **As to claim 80**, Conrad discloses a method step wherein the appliance is made of an elastic spring memory material (**see column 5 lines 50-55**).
20. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
21. Claims **82 through 90** are rejected under 35 U.S.C. 102(e) as being anticipated by Metzger et al. (US 2003/0149488).

22. As to **claim 82**, Metzger discloses an apparatus that comprises an appliance **110** (see **figures 6 and 7**) comprising two elongated curved elements each having a substantially circular dimension between a first end and a second end extending through more than 90 degrees of a circle (see **figures 6 and 7, pages 3 and 4 paragraphs 0041, 0042 and 0043; the plurality of braids makeup the twp elongated elements**), the two elements being coupled together at respective first and second ends (see **page 4 paragraph 0043**), the appliance being sized and structured to be placed in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal with the length of at least one of the elongated elements extending generally laterally across the posterior wall and, when so placed, being effective in treating at least one of sleep apnea and snoring (see **figures 6 and 7**).

23. As to **claim 83**, Metzger discloses an apparatus wherein the substantially circular dimension between the first and the second ends extends through at least 180 degrees of a circle (see **figures 6 and 7**).

24. As to **claim 84**, Metzger discloses an apparatus wherein each of the curved elements has a curved length extending from the first end to the second end, and the first end and the second end defining a gap therebetween extending outwardly away from the first and second curved elements having length which is reduced relative to the curved length of each of the curved elements (see **figures 6 and 7**).

25. As to **claim 85**, Metzger discloses an apparatus wherein each of the two elongated elements comprises a resilient wire (see **page 4 paragraph 0043**).

26. As to **claim 86**, Metzger discloses an apparatus wherein the appliance comprises a substantially c-shaped structure (see **figures 6 and 7**).

27. As to **claim 87**, Metzger discloses an apparatus wherein the two elongated elements are portions of the same structure (see **figures 6 and 7**).

28. As to **claim 88**, Metzger discloses an apparatus wherein the appliance as a lateral dimension defined by the distance between the first and second ends and a maximum longitudinal dimension perpendicular to the lateral dimension which is less than the lateral dimension (see **figures 6 and 7**).

29. As to **claim 89**, Metzger discloses an apparatus wherein the appliance has a concave loop configuration when the appliance is so placed in an oropharyngeal region (see **figures 6 and 7**).

30. As to **claim 90**, Metzger discloses an apparatus wherein the appliance is made of a biocompatible material (see **page 3 paragraph 0042**).

Claim Rejections - 35 USC § 103

31. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

32. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

33. Claims **72, 81, 91 and 92** are rejected under 35 U.S.C. 103(a) as being unpatentable over Conrad (US 6,250,307) in view of Metzger et al. (US 2003/0149488).

34. Referring to claim **72**, Conrad discloses the applicant's invention as claimed with the exception of providing at least two elements that are portions of the same structure. Metzger discloses an apparatus that does provide at least two elements that are portions of the same structure. Therefore it would have been obvious to modify Conrad's invention by providing at least two elements that are portions of the same structure as taught by Metzger in order to reduce airway collapse as a treatment for sleep apnea.

35. As to claims **81 and 92**, Conrad discloses a method wherein the appliance can be made of nitinol (see column 7 lines 5-20).

36. As to claim **91**, Conrad discloses a method step wherein the appliance is made of an elastic spring memory material (see column 5 lines 50-55).

Response to Arguments

37. Applicant's arguments filed on July 12, 2006 have been fully considered but they are not persuasive. The applicant argues that Conrad does not disclose, teach or even suggest a method for treating at least one of sleep apnea and snoring comprising providing an appliance in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal. The examiner disagrees. Conrad does disclose a method for treating at least one of sleep apnea and snoring (see summary of invention) that comprises providing an appliance in or radially outwardly from the lateral and posterior walls of an oropharyngeal region of a human or animal (see column 3 lines 45-55 and column 4 lines 30-45; in a broad definition

oropharyngeal region can be defined as a part of the pharynx between the soft palate and the upper edge of the epiglottis; see dictionary.com).

38. The applicant also argues that Metzger does not disclose, teach or suggest an appliance comprising two elongated curved elements each having a substantially circular dimension between a first end and a second end extending through more than 90 degrees of a circle with the two elements being coupled together at respective first and second ends and being spaced apart from each other between first and second ends. The examiner disagrees. Metzger does disclose an appliance that comprises two elongated curved elements each having a substantially circular dimension between a first end and a second end extending through more than 90 degrees of a circle (see figures 6 and 7, pages 3 and 4 paragraphs 0041, 0042 and 0043; the plurality of braids makeup the two elements), with the two elements being coupled together at respective first and second ends (see page 4 paragraph 0043) and being spaced apart from each other between the first and second ends.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event,

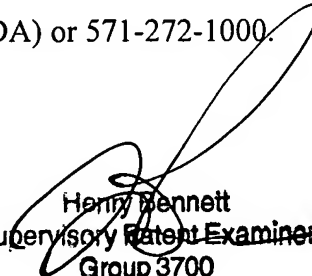
however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nihir Patel whose telephone number is (571) 272-4803. The examiner can normally be reached on 7:30 to 4:30 every other Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Henry Bennett can be reached on (571) 272-4791. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

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